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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,761	09/15/2003	J. Christopher Flaherty	59249-157 (INSL-125DV)	1492

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INSULET CORPORATION
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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,761

Applicant(s)

FLAHERTY ET AL.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-79, 82 and 83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-79, 82 and 83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:1/2006;4/2004;1/2004;11/2003;11/2003.

DETAILED ACTION

Claim Objections

1. Claim 48 is objected to because of the following informalities: in the second line of the second paragraph an article is missing before "strut". Appropriate correction is required.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 31-79, 82 and 83 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

a. Claims 1-22 of U.S. Patent No. 6,723,072.

b. Claims 1-135 of U.S. Patent No. 6,656,158

Although the conflicting claims are not identical, they are not patentably distinct from each other because the application is simply a broader recitation of the previously patented invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 31-33,36-42, 49-59, 61-65, and 69-79 are rejected under 35 U.S.C. 102(e) as being anticipated by HALLER (US 7,070,577).

Regarding claims 31 and 61, Haller teaches A device for delivering fluid to a patient, comprising: an exit port assembly (35); a dispenser (generally the upper portion of the device shown in figure 2A) including, a container (45) having an outlet (generally path 50) connected to the exit port assembly, an inlet (Fig 3A) for connection to a reservoir, and a side wall (44) extending along a longitudinal axis towards the outlet and the inlet, and a plunger assembly (42) received in the container and including, a first lateral segment (53) extending laterally with respect to the longitudinal axis of the container and contacting the side wall of the container, a second lateral segment (54) positioned between the first lateral segment and the outlet of the container, the second lateral segment extending laterally with respect to the longitudinal axis of the container and contacting the side wall of the container, and longitudinally spaced from the first lateral segment, and a shape memory element (41) having a changeable length decreasing from an uncharged length to a charged length when at least one charge is applied to

Art Unit: 3767

the shape memory element, the shape memory element connecting the first and the second lateral segments.

Regarding claims 32,39,40,58,59 the shape memory element (SME) is a one- or two-way nickel and titanium alloy (Nitinol) with a predetermined charged and uncharged length

Regarding claim 33, the SME is connected to the first and second lateral segments

Regarding claim 36, the SME is a collapsible bellows

Regarding claims 37 and 38, 62 and 63, the plunger assembly includes a rigid projection (42) with a predetermined length

Regarding claims 41 and 64, the plunger assembly does not rotating with respect to the side wall (Figs 3A-3B)

Regarding claims 42 and 65, the first lateral segment is fixed to the container.

Regarding claims 49-51 and 69-71, there is a reservoir (2) connected to the inlet of the dispenser, which contains insulin

Regarding claims 52 and 53, 72 and 73, the exit port assembly includes a patient access tool which is a needle

Regarding claims 54 and 55, 74 and 75, the device includes a local processor (10) with a battery

Regarding claims 56 and 57,76 and 77, the device includes a local processor (10), a wireless receiver (12) and a housing containing the dispenser (13), and a remote processor with transmitter (not shown)

Art Unit: 3767

Regarding claims 78 and 79, the plunger is activated by a solenoid or piezoelectric element.

6. Claims are rejected under 35 U.S.C. 102(e) as being anticipated by NASON (US 7,052,251).

Regarding claims 31 and 61, Nason teaches A device for delivering fluid to a patient, comprising: an exit port assembly (114); a dispenser including, a container (104) having an outlet (112) connected to the exit port assembly, an inlet (102) for connection to a reservoir, and a side wall (122) extending along a longitudinal axis towards the outlet and the inlet, and a plunger assembly (Fig 1B) received in the container and including, a first lateral segment (124) extending laterally with respect to the longitudinal axis of the container and contacting the side wall of the container, a second lateral segment (138) positioned between the first lateral segment and the outlet of the container, the second lateral segment extending laterally with respect to the longitudinal axis of the container and contacting the side wall of the container, and longitudinally spaced from the first lateral segment, and a shape memory element (130) having a changeable length decreasing from an uncharged length to a charged length when at least one charge is applied to the shape memory element, the shape memory element connecting the first and the second lateral segments.

Regarding claims 34,35 and 60, the shape memory element (SME) is a wire spring having a generally circular cross-section.

Art Unit: 3767

Regarding claims 43-45, the SMA acts as a cooler and heat sink or thermoelectric cooler as modulation of voltage accelerates cooling the wire to ambient temperature (Col 3 lines 53-62).

Regarding claims 46 and 66 there is an outlet valve (112)

Regarding claims 47 and 67 there is an inlet valve (106)

Regarding claims 48 and 68, 82 and 83, the side wall contains a first section (128) and a second section (136) with a strut (vertical portion of piece 136) See Fig 1A

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

Elyott Maxwell
9/8/06

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons